DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. Joel Orlinsky
Medical Research Laboratories, Inc.
1000 Asbury Drive
Buffalo Grove, IL 60089

Re: K002232
MRL AEDefibrillator
Regulatory Class: III (three)
Product Code: 74 MKJ, DRT, DPS
Dated: October 19, 2000
Received: October 20, 2000

Dear Mr. Orlinsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment III

.510(k) Number (if Known): K002232

Device Name: MRL AEDefibrillator

Indications For Use:

The MRL AEDefibrillator is intended to be used to treat patients in cardiopulmonary arrest. It is intended for use in either in-hospital or out-of-hospital arrests.

It is intended for use by personnel who are authorized by a physician/medical director, and who have the following training and skills:

Manual Mode:
- ✦ American Heart Association Advanced Cardiac Life Support certification or equivalent
- ✦ Training in the use of the MRL AEDefibrillator

Automatic Mode:
- ✦ American Heart Association Heartsaver course, American Red Cross CPR / AED course, or equivalent
- ✦ Training in the use of the MRL AED AEDefibrillator

In the automatic mode, it should only be used on patients who are unconscious, pulseless, and not breathing spontaneously. The automatic mode should not be used on children less than 80 kg. In the manual mode it is intended to treat patients from neo-natal to adult who are in ventricular fibrillation or pulseless ventricular tachycardia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODR)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002232

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109

(Optional Format 1-2-96)